

1 **10A NCAC 26E .0105 is proposed for amendment as follows:**

2 **10A NCAC 26E .0105 SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES**

3 (a) The following groups of activities are deemed to be independent of each other:

- 4 (1) manufacturing controlled substances;
- 5 (2) distributing controlled substances;
- 6 (3) dispensing controlled substances listed in Schedules II through V;
- 7 (4) conducting research [other than research described in Subparagraph (6) of this Paragraph] with
8 controlled substances listed in Schedules II through V;
- 9 (5) conducting instructional activities with controlled substances listed in Schedule II through V;
- 10 (6) conducting research with narcotic drugs listed in Schedules II through V for the purpose of continuing
11 the dependence on such drugs of a narcotic drug dependent person in the course of conducting an
12 authorized clinical investigation in the development of a narcotic addict rehabilitation program
13 pursuant to a notice of claims investigational exemption for a new drug approved by the Food and
14 Drug Administration;
- 15 (7) conducting research and instructional activities with controlled substances listed in Schedules I and
16 VI;
- 17 (8) conducting chemical analysis with controlled substances listed in any schedule;
- 18 (9) dispensing of controlled substances in Schedule III-V for opioid treatment; and
- 19 (10) possessing or training with controlled substances for the purpose of providing commercial detection
20 services.

21 (b) Any person who engages in more than one group of independent activities shall obtain a separate registration for
22 each group of activities except as provided in this Paragraph. Any person when registered to engage in the group
23 activities described in each Subparagraph of this Paragraph shall be authorized to engage in the coincident activities
24 described in that Subparagraph without obtaining a registration to engage in such coincident activities provided that
25 unless specifically exempted, the person complies with all requirements and duties prescribed by law for persons
26 registered to engage in such coincident activities as follows:

- 27 (1) A person registered to manufacture any controlled substance or basic class of controlled substance
28 shall be authorized to distribute that substance or class but no other substance or class which the
29 person is not registered to manufacture.
- 30 (2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be
31 authorized to conduct chemical analysis and preclinical research (including quality control analysis)
32 with narcotic and nonnarcotic controlled substances listed in those Schedules the person authorized to
33 manufacture.
- 34 (3) A person registered or authorized to conduct research with a basic class of controlled substances
35 listed in Schedules I and VI shall be authorized to manufacture such class if and to the extent that such
36 manufacture is set forth in the research protocol filed with the Drug Enforcement Administration and to

1 distribute such class to other persons registered or authorized to conduct research with such class or
2 registered or authorized to conduct chemical analysis with controlled substances.

3 (4) A person registered or authorized to conduct chemical analysis with controlled substances shall be
4 authorized to manufacture such substances for analytical or instructional purposes, to distribute such
5 substances to other persons registered or authorized to conduct chemical analysis or instructional
6 activities or research with such substances and to persons exempted from registration pursuant to Rule
7 .0111 of this Section and to conduct instructional activities with controlled substances.

8 (5) A person registered or authorized to conduct research [other than research described in Paragraph
9 (a)(6) of this Rule] with controlled substances listed in Schedules II through V shall be authorized to
10 conduct chemical analysis with controlled substances listed in those schedules in which the person is
11 authorized to conduct research, to manufacture such substances if and to the extent that such
12 manufacture is set forth in a statement filed with the application for registration and to distribute such
13 substances to other persons registered or authorized to conduct chemical analysis, instructional
14 activities or research with such substances and to persons exempted from registration pursuant to Rule
15 .0111 of this Section and to conduct instructional activities with controlled substances.

16 (6) A person registered to dispense controlled substances listed in Schedules II through V shall be
17 authorized to conduct research [other than research described in Paragraph (a)(6) of this Rule] and to
18 conduct instructional activities with those substances.

19 (c) A single registration to engage in any group of independent activities may include one or more controlled substances
20 listed in Schedules authorized in that group of independent activities. A person registered to conduct research with
21 controlled substances listed in Schedules I and VI may conduct research with any substance listed in Schedules I and VI
22 for which the person has filed an approved ~~a~~ research protocol from the Drug Enforcement Administration.

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24 *History Note: Authority G.S. 90-100; 90-101; 143B-210(9);*
25 *Eff. June 30, 1978;*
26 *Amended Eff. January 1, 2005.*
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